

K072609

**510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)**

**Submitted by:** Irvine Scientific Sales Co., Inc.  
2511 Daimler Street  
Santa Ana, CA 92705-5588

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Contact: Wendell Lee

Date Submitted: September 14, 2007

**Device Identification:**

Trade Name: Single Step Medium  
Common Name: In vitro embryo culture medium  
Classification Name: Reproductive Media (21 CFR, 884.6180)

**Predicate Device:**

Final Rule, 63 FR 48428, Docket number 97N-0335  
MultiBlast Medium (K034063)  
global<sup>®</sup>: fertilization, embryo culture and transfer medium (K053552)

**Description:**

Single Step Medium is a synthetic, defined medium, composed of a balance mixture of salts, amino acids, minerals and other nutrient substances designed to be used during fertilization and culture of zygote/embryo through the desired development stage (up to 5/6 days) in vitro.

Single Step Medium

**Intended Use:**

Single Step Medium is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of Single Step Medium as a culture medium from fertilization through day 5/6 of embryo development in vitro.

**Technological Characteristics:**

After allowing the fertilized zygote to develop in vitro in Single Step Medium, the embryo is removed from the culture dish. It is placed into a fresh dish containing Single Step Medium, and protein supplementation. The dish is then returned to the incubator, and the embryo is allowed to continue develop in vitro. The media is replenished after forty-eight (48) hours with fresh media and the embryo is further incubated until the desired stage of development has been achieved (up to 5/6 days) in vitro. After the desired stage of development is obtained the embryo is implanted into the patient.

**Performance Data:**

Single Step Medium is assayed by mouse embryo assay prior to release to market. This assay assures that the product is both functional for its intended use, the support of embryonic growth, and that no toxic components are present in the formulation. MultiBlast Medium (K034063) has been used in a variety of clinical settings, for its intended use, for a number of years. In that time, the product has become the one of the standard media used as the second, more complex stage of a sequential media protocol.

**Additional Information:**

Mouse embryo testing will be performed as a condition of release for this product, as well as endotoxin and sterility testing. Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling.

**Conclusion:**

The conclusion from performance testing, as well as a review of the historical information contained in professional literature in addition to the comparison to the predicate devices show that Single Step Medium is suitable for its intended use, and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335. References are presented in Appendix F.

Product Name	K #	Fertilization Medium	Culture of Embryos from Day 3 to 5/6	Culture of Embryos up to Day 5/6	Transfer Medium
Single Step Medium	K072609	✓		✓	
MultiBlast Medium	K034063		✓		
global <sup>®</sup> : fertilization, embryo culture and transfer medium	K053552	✓		✓	✓



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 12 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Wendell Lee, Pharm.D.  
Vice President, Regulatory Affairs/Quality Systems  
Irvine Scientific Sales Co., Inc.  
2511 Daimler Street  
SANTA ANA CA 92705-5588

Re: K072609  
Trade/Device Name: Single Step Medium  
Regulation Number: 21 CFR §884.6180  
Regulation Name: Reproductive media and supplements  
Regulatory Class: II  
Product Code: MQL  
Dated: January 28, 2008  
Received: January 29, 2008

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K07 2609Device Name: Single Step Medium

## Indications for Use:

Single Step Medium is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of Single Step Medium as a culture medium from fertilization through day 5/6 of embryo development in vitro.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)Page 1 of       

Margaret Bragdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K072609

Single Step Medium